

# Genetic Information: Legal Issues Relating to Discrimination and Privacy

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## Summary

In April 2003, the sequence of the human genome was deposited into public databases. This milestone, which has been compared to the discoveries of Galileo, and other advances in genetics have created novel legal issues relating to genetic information. The Human Genome Project produced detailed maps of the 23 pairs of human chromosomes and sequenced 99% of the three billion nucleotide bases that make up the human genome. The sequence information should aid in the identification of genes underlying disease, raising hope for genetic therapies to cure disease, but this scientific accomplishment is not without potential problems. For instance, the presence of a specific genetic variation may indicate a predisposition to disease but does not guarantee that the person will manifest the disease: How should an employer or insurer respond? The ethical, social and legal implications of these technological advances have been the subject of significant scrutiny and concern.

The legal implications of such information have been addressed in various ways largely by states, but also by Congress. The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, is the first federal law to specifically address discrimination and insurance issues relating to genetic discrimination. Congress is currently considering genetic discrimination legislation. H.R. 493, the Genetic Information Nondiscrimination Act of 2007 (GINA), was introduced in the 110<sup>th</sup> Congress by Representative Slaughter and 143 cosponsors on January 16, 2007. It passed the House on April 25, 2007. A companion bill, S. 358, 110<sup>th</sup> Congress, was introduced by Senator Snowe and 22 cosponsors on January 22, 2007, and has been reported out of the Senate Labor and Human Resources Committee. On March 5, 2008, the text of H.R. 493 as passed by the House was added to the end of the Paul Wellstone Mental Health and Addiction Equity Act of 2007 (H.R. 1424) in the engrossment of H.R. 1424. On April 24, 2008, the Senate took up H.R. 493, replaced the existing language with an amendment in the nature of a substitute, and passed the measure, as amended, by a vote of 95-0. The House is expected to pass H.R. 493 (as amended) during the week of April 28, 2008.

In the 109<sup>th</sup> Congress, S. 306, the Genetic Information Nondiscrimination Act of 2005, was passed on February 17, 2005, by a vote of 98-0. A companion bill, H.R. 1227, was introduced on March 10, 2005, and another bill, H.R. 6125 was introduced on September 20, 2006. In the 108<sup>th</sup> Congress, the Senate passed the Genetic Information Nondiscrimination Act of 2003, S. 1053. H.R. 1910 was introduced in the House and hearings were held, but the bill was not passed in the 108<sup>th</sup> Congress. This report discusses current federal law, state statutes, and legislation. It will be updated as needed.

## Contents

Background .....	1
Discrimination .....	6
The Health Insurance Portability and Accountability Act of 1996 (HIPAA) .....	6
The Americans with Disabilities Act.....	6
Overview .....	6
EEOC Interpretation of the ADA Regarding Genetic Discrimination .....	7
Supreme Court ADA Decisions .....	9
The ADA and Health Insurance .....	12
Executive Order.....	12
Privacy.....	14
Constitutional Protections .....	14
Federal Statutes .....	14
Privacy Act of 1974 .....	14
The Freedom of Information Act (FOIA) .....	15
The Americans with Disabilities Act (ADA) .....	15
The Health Insurance Portability and Accountability Act (HIPAA) .....	15
State Statutes .....	16
Federal Legislation .....	17
Legislation in the 110 <sup>th</sup> Congress .....	17
Legislation in the 109 <sup>th</sup> Congress .....	19
Legislation in the 108 <sup>th</sup> Congress .....	19
Legislation in the 107 <sup>th</sup> Congress .....	20
Legislation in the 106 <sup>th</sup> Congress .....	20

## Contacts

Author Information.....	22
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## Background

In April 2003, the sequence of the human genome was deposited into public databases. Scientists involved in the Human Genome Project (HGP)<sup>1</sup> reported that the finished sequence consists of overlapping fragments covering 99% of the coding regions of the human genome, with an accuracy of 99.999%.<sup>2</sup> These rapid advances provide powerful tools for determining the causes, and potentially the cures, for many common, complex diseases such as diabetes, heart disease, Parkinson's disease, bipolar illness, and asthma.

In congressional testimony Dr. Francis Collins, the Director of the National Human Genome Research Institute, described the potential the information generated by the HGP holds for medicine and public health. He stated that "The human genome sequence provides foundational information that now will allow development of a comprehensive catalog of all of the genome's components, determination of the function of all human genes, and deciphering of how genes and proteins work together in pathways and networks. Completion of the human genome sequence offers a unique opportunity to understand the role of genetic factors in health and disease, and to apply that understanding rapidly to prevention, diagnosis, and treatment. This opportunity will be realized through such genomics-based approaches as identification of genes and pathways and determining how they interact with environmental factors in health and disease, more precise prediction of disease susceptibility and drug response, early detection of illness, and development of entirely new therapeutic approaches."<sup>3</sup>

As Collins stated, with completion of the human genome sequence, scientists will now focus on understanding the clinical and public health implications of the sequence information. All disease has a genetic component and therefore genomic research has the potential to substantially reduce the collective burden of disease in the general population. Clinical genetic tests are becoming available at a rapid rate, with 1,013 clinical genetic tests currently available.<sup>4</sup> In addition, private insurers are beginning to include some clinical genetic tests in their health insurance benefits packages as evidence of the tests' clinical validity accumulates.<sup>5</sup> For example, some health plans have coverage policies for specific conditions, such as hereditary cancer testing, Cystic Fibrosis, Tay Sachs disease, and hereditary hemochromatosis.

These scientific advances in genetics, while promising, are not without potential problems. The ethical, social and legal implications of genetic research have been the subject of significant scrutiny and a portion of the funds for the Human Genome Project are set aside to support the analysis and research of these issues.<sup>6</sup> As scientific knowledge about genetics becomes

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<sup>1</sup> The Human Genome Project, begun in 1990, is a 13 year effort coordinated by the U.S. Department of Energy and the National Institutes of Health to identify all of the protein-coding genes in human DNA and to determine the sequences of the 3 billion chemical bases that make up human DNA, store this information in data bases, develop tools for data analysis, and address the ethical, legal, and social issues (ELSI) that may arise from the project. The Human Genome Project is funded through the Department of Energy and the National Institutes of Health. For more detailed information see "The National Human Genome Research Institute," <http://www.genome.gov/>, and "Human Genome Project Information,"

<sup>2</sup> "International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence," October, 20, 2004, at <http://www.genome.gov/12513430>.

<sup>3</sup> Testimony of Francis S. Collins, Director, National Human Genome Research Institute, National Institutes of Health, Before the Subcommittee on Health of the House Committee on Energy and Commerce (May 22, 2003).

<sup>4</sup> Gene Tests, available at <http://www.genetests.org/>.

<sup>5</sup> For more information on the status of genetic tests and further discussion of what constitutes 'genetic information,' see CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata.

<sup>6</sup> The group working on these issues is referred to as the Ethical, Legal and Social Implications (ELSI) program. See

increasingly widespread, numerous researchers and commentators, including Dr. Francis Collins, have expressed concerns about how this information will be used.<sup>7</sup> In congressional testimony, Dr. Collins stated: “while genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination....The misuse of genetic information has the potential to be a very serious problem, both in terms of people’s access to employment and health insurance and the continued ability to undertake important genetic research.”<sup>8</sup>

This concern has encompassed fear of discrimination in many aspects of life, including employment and health and life insurance. A study on discrimination found that a number of institutions, including health and life insurance companies, health care providers, blood banks, adoption agencies, the military and schools, were reported to have engaged in genetic discrimination against asymptomatic individuals.<sup>9</sup> The discriminatory practices included allegedly treating a genetic diagnosis as a preexisting condition for insurance purposes, refusal by an adoption agency to allow a woman at risk for Huntington’s disease to adopt based on the woman’s genetic risk, and termination from employment after disclosure of a risk of Huntington’s disease.<sup>10</sup> Similarly, another study reported that twenty-two percent of the respondents indicated that they or a family member were refused health insurance as a result of a genetic condition.<sup>11</sup>

Both the U.S. Chamber of Commerce and America’s Health Insurance Plans (AHIP) have countered that there is no convincing evidence that employers or insurers engage in genetic discrimination and that federal legislation to prohibit discrimination based on genetic information is unnecessary.<sup>12</sup> Larry Lorber, representing the U.S. Chamber of Commerce, stated in congressional testimony that “There is little to no evidence of employer collection or misuse of genetic information in today’s workplace. This is despite continued predictions that, in the absence of a bill, the fear of increased insurance costs, absenteeism, and low productivity would inevitably drive vast numbers of employers to genetic testing of the workforce and employment discrimination based on genetic makeup. Whether it is due to the threat of liability under existing protections, fear of public backlash, moral concerns or simply a lack of interest, employer collection and misuse of genetic information remains largely confined to the pages of science

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<http://www.genome.gov/page.cfm?pageID=10001618>.

<sup>7</sup> Testimony by Dr. Francis Collins, Director, National Center for Human Genome Research, Before the Senate Committee on Labor and Human Resources (March 6, 1996). See also, Hudson, Rothenberg, Andrews, Kahn, and Collins, “Genetic Discrimination and Health Insurance: An Urgent Need for Reform,” 270 *Science* 391 (Oct. 20, 1995); Annas, Glantz and Roche, “Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations,” 23 *J. of Law, Medicine and Ethics* 360 (1995); Gostin, “Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers,” 17 *Am. J. of Law & Med.* 109 (1991); Rothstein, Mark, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997).

<sup>8</sup> Testimony of Francis S. Collins, Director, National Human Genome Research Institute, National Institutes of Health, Before the Senate Health, Education, Labor and Pensions Committee (July 20, 2000).

<sup>9</sup> Geller, Alper, Billings, Barash, Beckwith, and Natowicz, “Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis,” 2 *Science and Engineering Ethics* 71 (1996). The study has been criticized by the insurance industry as relying on anecdotal information. See American Council of Life Insurance, “Statement Regarding the Council for Responsible Genetics ‘Study’ on Genetic Discrimination” (April 11, 1996).

<sup>10</sup> *Id.*

<sup>11</sup> Lapham, E. Virginia, Kozma, Chahira, Weiss, Joan O., “Genetic Discrimination: Perspectives of Consumers,” 274 *Science* 621 (October 25, 1996).

<sup>12</sup> “Testimony of the HIAA on Genetic Testing,” Before the Senate Committee on Labor and Human Resources, 105<sup>th</sup> Cong., 2d Sess. (May 21, 1998).

fiction.” He goes on to state that, “the current body of Federal law, including the ADA, Title VII of the Civil Rights Act, HIPAA and other Federal laws are more than ample to deal with any misuse of genetic information.”<sup>13</sup> In discussions with the Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS), the Chamber stated that while it does not believe that employers are engaging in genetic discrimination, it does recognize that the fear of potential discrimination may warrant a legislative solution.<sup>14</sup> In addition, America’s Health Insurance Plans states that, “As a matter of practice, health insurance plans do not use or disclose such private health information [genetic information] for purposes outside of normal insurance coverage activities. Moreover, federal and state laws currently prohibit the inappropriate use of genetic information.”<sup>15</sup>

Legal cases of genetic discrimination have been few. However, studies have shown that public fear of discrimination is substantial and negatively influences the uptake of genetic testing and the use of genetic information by consumers and health professionals. SACGHS learned that 68% of Americans are concerned about who would have access to their personal genetic information; 31% state this concern would prevent them from having a genetic test; and 68% agree that insurers would do everything possible to use genetic information to deny health coverage.<sup>16</sup> A 2004 survey conducted by the Genetics and Public Policy Center found that 92% of Americans oppose employer access to personal genetic information and 80% oppose access to this information by health insurers.<sup>17</sup> In addition, SACGHS as well as its predecessor Committee, the Secretary’s Advisory Committee on Genetic Testing (SACGT), sponsored two public forums to gather perspectives on genetic discrimination. Many comments were received from patients, consumers, health professionals, scientists, genetic test developers, educators, industry representatives, policymakers, lawyers, students and others representing a wide range of diverse ethnic and racial groups.<sup>18</sup> The comments and testimony revealed several anecdotal cases of discrimination. SACGT sent two letters to the Secretary of HHS urging support for nondiscrimination protections:

During consultations with the public SACGT heard from many Americans who are concerned about the misuse of genetic information by third parties, such as health insurers and employers, and the potential for discrimination based on that information. Many stated that fear of genetic discrimination would dissuade them from undergoing a genetic test or participating in genetic research studies. Others stated that they would pay out of pocket for a genetic test to prevent the results from being placed in their medical record. Such

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<sup>13</sup> Testimony of Lawrence Lorber, on behalf of the U.S. Chamber of Commerce, Before the Subcommittee on Employer-Employee Relations of the House Committee on Education and the Workforce (July 22, 2004).

<sup>14</sup> Meeting of the Secretary’s Advisory Committee on Genetics, Health, and Society. February 27, 2005. Accessed at <http://www4.od.nih.gov/oba/SACGHS/meetings/Feb2005/MasnyBerry.pdf>.

<sup>15</sup> America’s Health Insurance Plans (AHIP). “Use of Genetic Information” at <http://www.ahip.org/content/default.aspx?bc=39|34|326>.

<sup>16</sup> Meeting of the Secretary’s Advisory Committee on Genetics, Health, and Society. October 2005. Accessed at <http://www4.od.nih.gov/oba/SACGHS/meetings/October2005/10-20%20Public%20Attitudes%20toward%20Advances%20in%20Genetics-White.pdf>.

<sup>17</sup> Testimony of Kathy Hudson, Director, Genetics and Public Policy Center, before the Secretary’s Advisory Committee on Genetics, Health, and Society. Accessed at [http://82.165.149.27/news.eneews.article.php?action=detail&newsletter\\_id=16&article\\_id=55&newsletter\\_title=Issue+5](http://82.165.149.27/news.eneews.article.php?action=detail&newsletter_id=16&article_id=55&newsletter_title=Issue+5).

<sup>18</sup> Highlights and transcripts of January 27, 2000 testimony can be found on the SACGT website at <http://www4.od.nih.gov/oba/sacgt/sacgtmtg.htm>. Transcripts of the October 18, 2004 testimony can be found on the SACGHS website at <http://www4.od.nih.gov/oba/SACGHS/meetings/October2004/SACGHSOct2004postmeeting.htm>.

concerns are a deterrent to advances in the field of genetic testing and may limit the realization of the benefits of genetic testing.<sup>19</sup>

The SACGHS held a half day session where it heard testimony from members of the public, health care providers, insurers, employers and other stakeholders. This testimony revealed actual cases of genetic discrimination as well as considerable fear of genetic discrimination and altered behavior due to this fear. The Committee compiled the comments it received both orally and in writing, produced a DVD highlighting the oral testimony it received, and provided an extensive legal analysis concluding that current law does not provide adequate protection against genetic discrimination in health insurance and employment. This information was shared with the Secretary of HHS, with a recommendation that it also be shared with key Members of Congress. The Committee was interested in independently investigating the claims made by opponents that genetic discrimination was not occurring and that current law provides adequate protection against discrimination.

A joint report by the Department of Labor, the Department of Health and Human Services, the Equal Employment Opportunity Commission (EEOC) and the Department of Justice summarized the various studies on discrimination based on genetic information and argued for the enactment of federal legislation. The report stated that “genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work” and that “because an individual’s genetic information has implications for his or her family members and future generations, misuse of genetic information could have intergenerational effects that are far broader than any individual incident of misuse.”<sup>20</sup> Concluding that existing protections are minimal, the report went on to call for the enactment of legislation which states that (1) employers should not require or request that employees or potential employees take a genetic test or provide genetic information as a condition of employment or benefits, (2) employers should not use genetic information to discriminate against, limit, segregate, or classify employees, and (3) employers should not obtain or disclose genetic information about employees or potential employees under most circumstances.<sup>21</sup> According to the Labor Department report, employers should be able to (1) use genetic information for monitoring for the effects of a particular substance in the workplace under certain circumstances, and (2) disclose genetic information for research and other purposes with the written, informed consent of the individuals. In addition, the report states that the statutory authority of federal agencies or contractors to promulgate regulations, enforce workplace safety and health laws, or conduct occupational or other health research should not be limited.<sup>22</sup>

The National Council on Disability (NCD), an independent federal agency that advises the President and Congress on issues affecting individuals with disabilities, published a position paper arguing for the enactment of federal legislation prohibiting genetic discrimination on March 4, 2002. The NCD argues that recent advances in genetic research have brought an increasing

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<sup>19</sup> From a letter from SACGT to Secretary Tommy Thompson, May 3, 2001, at [http://www4.od.nih.gov/oba/sacgt/ltr\\_to\\_secDHHS5-3-01.pdf](http://www4.od.nih.gov/oba/sacgt/ltr_to_secDHHS5-3-01.pdf).

<sup>20</sup> Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, “Genetic Information and the Workplace,” <http://www.dol.gov/oasam/programs/history/herman/reports/genetics.htm> 2-3 (January 20, 1998).

<sup>21</sup> Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, “Genetic Information and the Workplace,” <http://www.dol.gov/oasam/programs/history/herman/reports/genetics.htm> at 7 (January 20, 1998).

<sup>22</sup> *Id.*



potential for genetic discrimination, that genetic discrimination is a historical and current reality, that genetic discrimination undermines the purposes of genetic research and testing, that genetic test information has little value for purposes of making employment decisions and insurance decisions, and that existing laws are insufficient to protect individuals from genetic discrimination.<sup>23</sup>

President Bush has also made the prohibition of genetic discrimination one of the key components of his health care reform agenda. In his June 2001 radio address to the nation, the President stated that, “Genetic discrimination is unfair to workers and their families. It is unjustified - among other reasons, because it involves little more than medical speculation. A genetic predisposition toward cancer or heart disease does not mean the condition will develop. To deny employment or insurance to a healthy person based only on a predisposition violates our country’s belief in equal treatment and individual merit.”<sup>24</sup> The Administration has indicated that it favors enactment of legislation to prohibit the improper use of genetic information in health insurance and employment.<sup>25</sup>

It should be emphasized that legal issues relating to genetics may vary depending on whether insurance, employment or other types of discrimination, or medical research are involved. Approaches to addressing the issues raised in these contexts vary from taking no legislative action, addressing certain specific concerns (as was done in the Health Insurance Portability and Accountability Act), or more far reaching approaches such as comprehensive legislation on genetics or legislation focused on all medical records, including genetic information.

Generally legal issues raised regarding genetics have been based on two main concepts: privacy and discrimination. The privacy interests of an individual in his or her genetic information have been seen as significant and protecting these interests is seen as making discriminatory actions based on this information less likely. However, another approach would be to prohibit this potential misuse of the information by prohibiting discrimination. Some statutes, like the Americans with Disabilities Act (ADA), 42 U.S.C. §§ 12101 et seq., take a two-pronged approach to similar issues regarding medical information about disabilities by both protecting the confidentiality of the information and by prohibiting discriminatory acts.

Currently there are no federal laws that directly and comprehensively address the issues raised by the use of genetic information. There are, however, a few laws that address parts of these issues but the only federal law that directly addresses the issue of discrimination based on genetic information is the Health Insurance Portability and Accountability Act (HIPAA). On February 8, 2000, President Clinton issued an executive order prohibiting discrimination against federal employees based on protected genetic information. On December 20, 2000, the Department of Health and Human Services issued final regulations on medical privacy which are not specific to genetics but cover all personal health information, including genetic information.<sup>26</sup> This rule went into effect on April 14, 2001 but was amended in 2002.<sup>27</sup> In addition, many states have enacted laws which vary widely in their approaches to the protection of genetic information.

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<sup>23</sup> National Council on Disability, “Position Paper on Genetic Discrimination Legislation”

<sup>24</sup> President George W. Bush. Presidential Radio Address. June 23, 2001. Accessed at <http://www.npaf.org/initiatives.php?p=95>.

<sup>25</sup> See <http://www.whitehouse.gov/news/releases/2007/01/print/20070117-1.html>.

<sup>26</sup> 65 Fed. Reg. 82460 (Dec. 20, 2000).

<sup>27</sup> See *infra* pp. 14-16 for a more detailed discussion.



## Discrimination

### The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

P.L. 104-191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA),<sup>28</sup> has been hailed as taking “important steps toward banning genetic discrimination in health insurance” but has also been criticized as not going far enough.<sup>29</sup> The act prohibits a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provides that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. It also prohibits a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. These protections apply to individuals within the group plans; they do not apply to the acceptance of the whole group or to the premiums set for the group. Thus, HIPAA prohibits group health plans or issuers of group health plans from charging an individual a higher premium than a similarly situated individual; however, the law does not prevent an entire group from being charged more.

The act would not prohibit group health plans or issuers of plans (i.e., insurers) from requiring or requesting genetic testing, does not require them to obtain authorization before disclosing genetic information, and does not prevent them from excluding all coverage for a particular condition or imposing lifetime caps on all benefits or on specific benefits. In addition, this act does not apply to individual health insurance policies, and does not address the issues of the use of genetic information in contexts other than health insurance such as employment.<sup>30</sup>

### The Americans with Disabilities Act

#### Overview

The Americans with Disabilities Act (ADA), 42 U.S.C. § 12101 et seq., prohibits discrimination against an individual with a disability in employment, public services, public accommodations, and communications. The threshold issue in any ADA case is whether the individual alleging discrimination is an individual with a disability. The act defines the term disability with respect to an individual as having “(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual, (B) a record of such an impairment; or (C) being regarded as having such an impairment.”<sup>31</sup> Although the statutory language of the ADA does not

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<sup>28</sup> For a general discussion of this act see CRS Report RL31634, *The Health Insurance Portability and Accountability Act (HIPAA) of 1996: Overview and Guidance on Frequently Asked Questions*, by Hinda Chaikind et al. For a more detailed discussion of HIPAA and genetic discrimination see Robert B. Lanman, “An Analysis of the Adequacy of Current Law in Protecting Against Genetic Discrimination in Health Insurance and Employment,” at <http://www4.od.nih.gov/oba/sacghs/reports/reports.html#discrimination>.

<sup>29</sup> Statement of Rep. Louise Slaughter Before the House Science Subcommittee on Technology, Hearing on Technological Advance in Genetic Testing: Implications for the Future, September 17, 1996.

<sup>30</sup> It should also be noted the HIPAA contains certain requirements regarding the standardization of claims that raise potential privacy issues. HIPAA addressed these issues by requiring either congressional action or regulatory action to protect privacy. A more detailed discussion of this issue is contained in the section on privacy.

<sup>31</sup> 42 U.S.C. § 12102.

reference genetic traits, there was a discussion of the issue during congressional debate.<sup>32</sup> So far there have been no judicial decisions but one case was brought by the EEOC and settled.<sup>33</sup> In addition, Terri Seargent filed with the EEOC alleging genetic discrimination and received a determination on November 21, 2000 that the EEOC's investigation supported her allegation of discrimination under the ADA.<sup>34</sup>

## EEOC Interpretation of the ADA Regarding Genetic Discrimination

The ADA has been interpreted by the Equal Employment Opportunity Commission (EEOC) as including genetic information relating to illness, disease, or other disorders.<sup>35</sup> The legislative history was cited by the EEOC in its guidance to the definition of disability for its compliance manual. In this guidance, the EEOC examined the definition of disability under the ADA, noting that the definition was composed of three prongs: disability means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (2) a record of such an impairment, or (3) being regarded as having such an impairment.<sup>36</sup> It was under the third prong that the EEOC determined that discrimination based on genetic information relating to illness, disease, or other disorders was prohibited.<sup>37</sup>

Although this EEOC interpretation was widely heralded as a significant step for the protection of rights for individuals whose genes indicate an increased susceptibility to illness, disease or other

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<sup>32</sup> Rep. Owens stated that "[t]hese protections of the ADA will also benefit individuals who are identified through genetic tests as being carriers of a disease-associated gene. There is a record of genetic discrimination against such individuals, most recently during sickle cell screening programs in the 1970's. With the advent of new forms of genetic testing, it is even more critical that the protections of the ADA be in place. Under the ADA, such individuals may not be discriminated against simply because they may not be qualified for a job sometime in the future. The determination as to whether an individual is qualified must take place at the time of the employment decision, and may not be based on speculation regarding the future. Moreover, such individuals may not be discriminated against because they or their children might incur increased health care costs for the employer." 136 Cong. Rec. H 4623 (daily ed. July 12, 1990) (remarks of Rep. Owens). Similarly, Rep. Edwards and Rep. Waxman also stated that individuals who are carriers of a disease-associated gene may not be discriminated against under the ADA. 136 Cong. Rec. H 4625 (daily ed. July 12, 1990) (Statement of Rep. Edwards); *Id.* at H 4627 (Statement of Rep. Waxman).

<sup>33</sup> The EEOC alleged that Burlington Northern Sante Fe (BNSF) Railroad tested its employees for a genetic marker linked to carpal tunnel syndrome in an attempt to address a high number of repetitive stress injuries leading to employee compensation. The EEOC and BNSF reached a settlement agreement rejecting the testing of employees for the genetic marker. See Paul Miller, EEOC Commissioner, "Analyzing Genetic Discrimination in the Workplace," 12 Human Genome News (Feb. 2002) at [http://www.ornl.gov/sci/techresources/Human\\_Genome/publicat/hgn/v12n1/09workplace.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v12n1/09workplace.shtml).

<sup>34</sup> Testimony of Janiori Goldman before the House Committee on Energy and Commerce, Subcommittee on Health, 107<sup>th</sup> Cong., 1<sup>st</sup> Sess. (March 22, 2001).

<sup>35</sup> Equal Employment Opportunity Commission, Compliance Manual, vol. 2, section 902, order 915.002,902-45 (1995). It is also possible that Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., may provide some protection against certain kinds of genetic discrimination since an argument could be made that discrimination based on genetic disorders that are racially or ethnically based, such as sickle cell disease, is prohibited under Title VII. There are relatively few genetic conditions that have a strong connection with a racial or ethnic group, thus limiting the scope of potential coverage. However, in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998), blood tests for sickle cell trait were found to give rise to a Title VII claim.

<sup>36</sup> 42 U.S.C. § 12102(2).

<sup>37</sup> The EEOC gave the following example of its application of the third prong of the definition to genetic discrimination. CP's genetic profile reveals an increased susceptibility to colon cancer. CP is currently asymptomatic and may never in fact develop colon cancer. After making CP a conditional offer of employment, R learns about CP's increased susceptibility to colon cancer. R then withdraws the job offer because of concerns about matters such as CP's productivity, insurance costs and attendance. R is treating CP as having an impairment that substantially limits a major life activity. Accordingly CP is covered by the third part of the definition of disability.

disorders, it is limited in its application and may be even more limited after the recent Supreme Court decisions on the definition of disability.<sup>38</sup> However, the EEOC has not withdrawn this guidance and at Senate hearings, EEOC Commissioner Paul Miller stated that the ADA “can be interpreted to prohibit employment discrimination based on genetic information. However, the ADA does not explicitly address the issue and its protections are limited and uncertain.” In addition, Commissioner Miller observed that even if the ADA were found to cover genetic discrimination, the requirements of the ADA may not protect workers from all types of genetic discrimination. He stated, “for example, the ADA does not protect workers from requirements or requests to provide genetic information to their employers....In addition, once the applicant is hired, the employer may request that the employee take a medical exam, such as a genetic test, if the employer can demonstrate that the information from that test is job related and consistent with business necessity.”<sup>39</sup>

The first ADA case alleging genetic discrimination was filed with the EEOC by Terri Seargent. Ms. Seargent, whose situation was extensively discussed during Senate debate on genetic discrimination in the 106<sup>th</sup> Congress, had a promising career as a manager for a small insurance broker in North Carolina. She had positive performance evaluations but after medical tests determined that she had Alpha 1 Antitrypsin Deficiency, a condition that affects the lungs and liver, and she began taking expensive medication, she was terminated from her employment.<sup>40</sup> Ms. Seargent filed with the EEOC alleging genetic discrimination and received a determination on November 21, 2000 that the EEOC’s investigation supported her allegation of discrimination under the ADA.<sup>41</sup>

The EEOC settled its first court action challenging the use of workplace genetic testing under the ADA against Burlington Northern Santa Fe Railway (BNSF). The settlement, announced on April 18, 2001, ended genetic testing of employees who filed claims for work-related injuries based on carpal tunnel syndrome. EEOC Commissioner Paul Steven Miller stated “The Commission will continue to respond aggressively to any evidence that employers are asking for or using genetic tests in a manner that violates the ADA. Employers must understand that basing employment decisions on genetic testing is barred under the ADA’s ‘regarded as’ prong, as stated in EEOC’s

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<sup>38</sup> Prior to the Supreme Court’s decisions there were three major limitations on the EEOC interpretation. First, the ADA specifically excludes insurance from its coverage except that this exclusion “shall not be used as a subterfuge to evade the purposes of title I and III.” The exact parameters of this provision, especially as it relates to genetic information, are unclear although it would appear fair to say the nondiscrimination protections for individuals with certain genes would be considerably stronger in the employment context than when such individuals are being considered for insurance coverage. Second, the EEOC interpretation is part of guidance issued in its compliance manual. Specific prohibitions of discrimination in this area were not included in the statute and were also not part of the EEOC’s regulations. Even if a court gives deference to the guidance as indicative of the agency’s view of the statute, a court would not likely give such guidance the deference it would accord to statutory or regulatory language. In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Even if the prohibitions against discrimination in the ADA would apply, it would be difficult to prove that genetic information was the reason for discrimination.

<sup>39</sup> Statement of Commissioner Paul Steven Miller, U.S. Equal Employment Opportunity Commission, Before the Senate Committee on Health, Education, Labor and Pensions (July 20, 2000).

<sup>40</sup> 146 Cong. Rec. S6050 (daily ed. June 29, 2000)(remarks of Sen. Kennedy).

<sup>41</sup> Testimony of Janiori Goldman before the House Committee on Energy and Commerce, Subcommittee on Health, 107<sup>th</sup> Cong., 1<sup>st</sup> Sess. (March 22, 2001).

1995 policy guidance on the definition of the term ‘disability.’ Moreover, genetic testing, as conducted in this case, also violates the ADA as an unlawful medical exam.”<sup>42</sup>

## Supreme Court ADA Decisions

Although the combination of the ADA’s legislative history and the EEOC’s guidance has led commentators to argue that the ADA would cover genetic discrimination, the merit of these arguments has been uncertain since there have been no reported cases holding that the ADA prohibits genetic discrimination. This uncertainty has increased in light of Supreme Court decisions on the definition of disability under the ADA.<sup>43</sup>

The first Supreme Court ADA case to address the definition of disability was *Bragdon v. Abbott*, a 1998 case involving a dentist who refused to treat an HIV infected individual outside of a hospital.<sup>44</sup> In *Bragdon*, the Court found that the plaintiff’s asymptomatic HIV infection was a physical impairment impacting on the major life activity of reproduction thus rendering HIV infection a disability under the ADA. In two 1999 cases the Court examined the definitional issue whether the effects of medication or assistive devices should be taken into consideration in determining whether or not an individual has a disability. The Court in the landmark decisions of *Sutton v. United Airlines*<sup>45</sup> and *Murphy v. United Parcel Service, Inc.*,<sup>46</sup> held, contrary to the interpretation given by the EEOC, that the determination of whether an individual has a disability should be made with reference to mitigating measures. In reaching this holding, the Court looked to the first prong of the definition of disability (having a physical or mental impairment that substantially limits one or more of the major life activities of an individual) and emphasized that the phrase “substantially limits” appears in the present indicative verb form “requiring that a person be presently—not potentially or hypothetically—substantially limited in order to demonstrate a disability....A person whose physical or mental impairment is corrected by medication or other measures does not have an impairment that presently ‘substantially limits’ a major life activity.”<sup>47</sup> In *Albertsons Inc. v. Kirkingburg*<sup>48</sup> the Court held unanimously that the ADA requires proof that the limitation on a major life activity by the impairment is substantial. The Court in *Sutton* also looked at the findings enacted as part of the ADA which stated that “some 43,000,000 Americans have one or more physical or mental disabilities” and found that this figure was inconsistent with the argument that the statute covered individuals without looking at the mitigating effects of medications or devices. The individualized nature of the inquiry into whether an individual was an individual with a disability was emphasized.

More recently the Court held in *Toyota Motor Manufacturing v. Williams*,<sup>49</sup> that to be an individual with a disability under the act, an individual must have substantial limitations that are central to daily life, not just limited to a particular job. The Court held that “to be substantially limited in performing manual tasks, an individual must have an impairment that prevents or severely restricts the individual from doing activities that are of central importance to most

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<sup>42</sup> <http://www.eeoc.gov/press/4-18-01.html>.

<sup>43</sup> For a discussion of the Supreme Court’s ADA decisions see CRS Report RL31401, *The Americans with Disabilities Act: Supreme Court Decisions*, by Nancy Lee Jones.

<sup>44</sup> 524 U.S. 624 (1998). For a more detailed discussion of this decision see CRS Report 98-599, *The Americans with Disabilities Act: HIV Infection is Covered Under the Act*, by Nancy Lee Jones.

<sup>45</sup> 527 U.S. 471 (1999).

<sup>46</sup> 527 U.S. 516 (1999).

<sup>47</sup> 527 U.S. 471, 482-483 (1999).

<sup>48</sup> 527 U.S. 555 (1999).

<sup>49</sup> 534 U.S. 184 (2002).

people's daily lives." Significantly, the Court also stated that "[t]he impairment's impact must also be permanent or long-term."

Although the Court's decision in *Sutton* did not turn on the third prong of the definition of disability (being "regarded as having such an impairment") the Court did address the interpretation of this part of the definition. There are two ways, the Court stated, that an individual can fall within the "regarded as" prong: (1) a covered entity mistakenly believes that a person has a physical impairment that substantially limits one or more major life activities, or (2) a covered entity mistakenly believes that an actual impairment substantially limits one or more major life activities. The Court found that, on its own, the allegation that an entity has a vision requirement in place does not establish a claim that the entity regards an individual as substantially impaired in the major life activity of working. The term "substantially limits" was regarded as significant. It requires "at a minimum, that plaintiffs allege they are unable to work in a broad class of jobs."<sup>50</sup> The Court emphasized that it was "assuming without deciding" that working is a major life activity and that the EEOC regulations interpreting "substantially limits" are reasonable and found that even using the EEOC interpretation, the plaintiffs in *Sutton* failed to allege adequately that their vision is regarded as an impairment that substantially limits them in a major life activity. Being precluded from being a global airline pilot was not sufficient since they could obtain other, although less lucrative jobs, as regional pilots or pilot instructors.

The "regarded as" prong was directly at issue in *Murphy*. In *Murphy* the Court held that the fact that an individual with high blood pressure was unable to meet the Department of Transportation (DOT) safety standards was not sufficient to create an issue of fact regarding whether an individual is regarded as unable to utilize a class of jobs. Like *Sutton*, the holding in *Murphy* emphasized the numerous other jobs available to the plaintiff.

The Supreme Court's decisions on the ADA did not directly address genetic discrimination and it is possible that the ADA could be interpreted to cover a particular genetic defect. However, the reasoning used in the Court's recent decisions appears to make it unlikely that an ADA claim based on genetic discrimination would be successful. There are several factors that lead to this conclusion.

First, the Supreme Court in *Sutton* specifically struck down an interpretation by the EEOC regarding the use of mitigating factors and raised questions concerning the validity of the EEOC's interpretation. The Court also found no statutory authority for agency interpretation of the definition of disability. The EEOC had taken the position that whether or not an individual has a disability should be determined by what his or her condition would be without medication or an assistive device. Rejecting this EEOC interpretation, in *Sutton* the Supreme Court noted that no agency was given the authority to interpret the term "disability" but that because both parties accepted the regulations as valid "we have no occasion to consider what deference they are due, if any." Similarly, in *Murphy* the Court clearly stated that its use of the EEOC regulations did not indicate that the regulations were valid. However, in its earlier decision in *Bragdon v. Abbott*, the Court had found its conclusion that HIV infection was covered by the ADA to be "reinforced by administrative guidance issued by the Justice Department...." The cases subsequent to *Bragdon* did not examine this seeming contradiction so exactly how a future decision would view EEOC regulations and guidance is uncertain. This issue is especially important regarding potential cases of genetic discrimination since the EEOC has published guidance indicating that the ADA covers genetic discrimination,<sup>51</sup> and there are no reported cases.

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<sup>50</sup> 527 U.S. 471, 491 (1999).

<sup>51</sup> EEOC Compliance Manual, Vol. 2, section 902, order 915.002,902-45 (1995).



Similarly, the Supreme Court showed little indication to examine the legislative history of the ADA. The Court in *Sutton* held that it was not necessary to consider the legislative history of the ADA regarding the issue of whether individuals should be examined in their uncorrected state or with the use of mitigating medications or devices. It found that the statutory language was sufficient to support its holding on this issue. Although the issue regarding genetic discrimination is distinct from that of the use of mitigating medications and devices, the Court's general reluctance to examine legislative history in *Sutton* may indicate that the language on genetic discrimination quoted above from the congressional debates also would not be examined.

The Court's reliance in *Sutton* upon the findings in the ADA that 43,000,000 Americans have one or more physical disabilities also indicates that the Court may not find genetic defects to be covered. The number of individuals cited in the findings as having a disability was seen by the Court as inconsistent with the argument that the statute covered individuals whose disabilities were mitigated by medications or devices. Since the prevalence of genetic defects is believed to be widespread, coverage of genetic defects could arguably include almost every individual. Thus, it is possible that the Court could use the same rationale as in *Sutton* to find genetic defects not included.

In *Bragdon v. Abbott*, where the Court found that HIV infection was covered under the ADA, the majority opinion spent considerable time discussing the immediate physiological effects of the infection. This would appear to be consistent with the holding in *Sutton* that the "substantially limits" definitional language requires that the substantial limitation not be potential or hypothetical. In addition, in *Toyota Motor Manufacturing v. Williams* substantial limitations were seen by the Court as those that are central to daily life, not just limited to a particular job. This reasoning could be contrasted to the situation presented by genetic defects which in many cases do not ever manifest. Interestingly, in his dissenting opinion in *Bragdon v. Abbott*, then Chief Justice Rehnquist, who was in the majority in *Sutton*, stated that the argument regarding coverage of HIV infection "taken to its logical extreme, would render every individual with a genetic marker for some debilitating disease 'disabled' here and now because of some possible future effects." Whether the Court would now share this view that such coverage of genetic discrimination is an invalid interpretation of the definition is uncertain, especially since the Court in *Bragdon* was discussing the first prong of the definition, not the "regarded as" prong which is the most likely basis for coverage of genetic defects.

In other cases the Court provided considerable guidance concerning the "regarded as" prong of the definition of disability, the most likely aspect of the definition to be used to find coverage of genetic defects. Including the requirement that the individual be regarded as "substantially limited" in a major life activity, the Court found that this language meant that being precluded from a particular job was not sufficient to be substantially limited in the major life activity of working if other jobs in the same class could be obtained. And when this specific issue was raised in *Murphy*, the plaintiff was not found to be regarded as substantially limited in the major life activity of working. The main point of this rather complicated discussion is that making the case that one is regarded as substantially limited in a major life activity, particularly the major life activity of working, is likely to be difficult.

The Supreme Court's decisions do not directly address ADA coverage of genetic discrimination. They emphasize an individualized approach to the determination of whether an individual has a disability under the ADA. Although an argument could be made that the ADA would cover individuals with genetic defects in certain cases, the Court's decisions, particularly *Sutton* and

*Murphy*, use reasoning that would make it unlikely that most ADA claims based on genetic discrimination would be successful.<sup>52</sup>

In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Assuming that the prohibitions against discrimination in the ADA would apply, it is difficult to prove that genetic information was the reason for discrimination. This raises issues relating to the privacy of genetic information.

## The ADA and Health Insurance

Title III of the ADA provides that no individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation.<sup>53</sup> A place of public accommodation is defined in part as an insurance office.<sup>54</sup> It could be argued that discrimination in insurance on the basis of genetic information would be a violation of Title III of the ADA.<sup>55</sup> However, such an argument would be limited since, in addition to the limitations of the definition of disability discussed previously, the ADA specifically states that Titles I through IV “shall not be construed to prohibit or restrict an insurer....from underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law.”<sup>56</sup> The ADA also provides that this provision “shall not be used as a subterfuge to evade the purposes of titles I and III.”<sup>57</sup> The issue of insurance was discussed by the Department of Justice in its technical assistance manual which observed that “[t]he ADA, therefore, does not prohibit use of legitimate actuarial considerations to justify differential treatment of individuals with disabilities in insurance.”<sup>58</sup> Thus, if an insurer uses legitimate actuarial considerations regarding providing insurance to an individual with a genetic condition, it is unlikely that there would be a violation of the ADA.

## Executive Order

On February 9, 2000, President Clinton signed Executive Order 13145 prohibiting genetic discrimination against employees in federal executive departments and agencies. In announcing

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<sup>52</sup> In testimony before the Senate Committee on Health, Education, Labor and Pensions, Andrew J. Imparato, the President and CEO of the American Association of People with Disabilities testified that “the ADA as drafted does provide some protections against genetic discrimination in employment, but the law has been interpreted by the Supreme Court and lower federal courts in a manner which weakens its protections. Whereas the ADA can be and has been used to stop genetic discrimination in some instances, the protections it affords offer little security to people with genetic markers and health conditions that have not yet developed into full-blown debilitating conditions.” Testimony of Andrew J. Imparato, “Protecting Against Genetic Discrimination: The Limits of Existing Laws,” Before the Senate Committee on Health, Education, Labor and Pensions, 107<sup>th</sup> Cong., 2d Sess. (Feb. 13, 2002), reprinted at [http://help.senate.gov/Hearings/2002\\_02\\_13/Imparato.pdf](http://help.senate.gov/Hearings/2002_02_13/Imparato.pdf).

<sup>53</sup> 42 U.S.C. § 12182.

<sup>54</sup> 42 U.S.C. § 12181(7)(F).

<sup>55</sup> For a more detailed discussion see Robert B. Lanman, “An Analysis of the Adequacy of Current Law in Protecting Against Genetic Discrimination in Health Insurance and Employment,” (May 2005) reproduced at <http://www4.od.nih.gov/oba/sacghs/reports/reports.html#discrimination>.

<sup>56</sup> 42 U.S.C. § 12201(c).

<sup>57</sup> *Id.*

<sup>58</sup> <http://www.ada.gov/taman3.html#III-3.11000>.



the executive order at a meeting of the American Association for the Advancement of Science, the President stated that “This extraordinary march of human understanding imposes on us a profound responsibility to make sure that the age of discovery can continue to reflect our most cherished values.”<sup>59</sup> Many commentators lauded the executive order, and quoted with approval its description as “preventive policy making—to put in place the kind of protections that the public needs and deserves before we find ourselves in a needless crisis situation.”<sup>60</sup> However, it has also been criticized both on a philosophical level<sup>61</sup> and in the details of its coverage.<sup>62</sup> The EEOC has issued guidance on the executive order.<sup>63</sup>

The executive order defines “protected genetic information” as “(A) information about an individual’s genetic tests; (B) information about the genetic tests of an individual’s family members; or (C) information about the occurrence of a disease; or medical condition or disorder in family members of the individual.” Current health status information would not be protected under this executive order unless it was derived from the information described above.

The executive order requires executive departments and agencies to implement the following nondiscrimination requirements:

- the employing entity shall not discharge, fail or refuse to hire, or otherwise discriminate against any employee because of protected genetic information or because of information about a request for or receipt of genetic services;
- the employing entity shall not limit, segregate or classify employees in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect that employee’s status because of protected genetic information or because of information about a request for or receipt of genetic services;
- the employing entity shall not request, require, collect, or purchase protected genetic information with respect to an employee or information about a request for or receipt of genetic services;
- the employing entity shall not disclose protected genetic information with respect to an employee or information about a request for or receipt of genetic services with certain exceptions;
- the employing entity shall not maintain protected genetic information or information about a request for or receipt of genetic services in general personnel

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<sup>59</sup> “President’s Order Bars Discrimination Based on Genetics,” *Investor’s Business Daily* A9 (February 9, 2000).

<sup>60</sup> Wendy R. Uhlmann, “When Genes are Decoded, Who Should See the Results?; Every one of us at Risk,” *The New York Times* F7 (February 29, 2000).

<sup>61</sup> Michael Kinsley, editor of Slate, an online magazine, observed that “genetic discrimination is universal, inevitable and, in some ways, essential.... Practice, practice will get you to Carnegie Hall, but only if you’ve been born on the right bus.... The world would be a poorer place if it did not distinguish between me and Yo-Yo Ma in doling out opportunities to be a concert cellist.” Michael Kinsley, “Genetic Correctness,” *The Washington Post* A29 (April 18, 2000).

<sup>62</sup> Mark A. Hall, a law professor at Wake Forest University, argues that the order’s prohibition of considering predictive genetic information would not allow for the screening of susceptibility to toxic exposure prior to working in such an environment and would not allow for the use of genetic predispositions to future conditions that could effect job performance. Mark A. Hall, “When Genes are Decoded, Who Should See the Results?; Many ‘Greatly Overestimate the Risk’,” *The Washington Post* F7 (February 29, 2000).

<sup>63</sup> <http://www.eeoc.gov/policy/docs/guidance-genetic.html>

files. Such materials shall be treated as confidential medical records and kept separate from personnel files.

There are certain exceptions to these prohibitions. For example, the employing entity may request or require information if such current condition could prevent the applicant or employee from performing the essential functions of the job, or where it is to be used exclusively to determine whether further medical evaluation is needed to diagnose a current disease. Genetic monitoring of biological effects of toxic substances in the workplaces are permitted in certain circumstances.

## Privacy

### Constitutional Protections

Although the Constitution does not expressly provide for a right to privacy, the Supreme Court has found some right to informational privacy.<sup>64</sup> However, these rights are limited by judicial deference to government's need to acquire the information and by the fact that such a constitutional right would be limited to state action. As a practical matter, this would mean that federal or state collections of information may receive some constitutional protection but the collection and use of information by private health plans or organizations would not be covered.<sup>65</sup>

The ninth circuit court of appeals in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*<sup>66</sup> touched upon privacy issues in the context of genetic information. The Lawrence Berkeley Laboratory, a research institution jointly operated by state and federal agencies, allegedly tested the blood and urine of its employees for several medical conditions, including sickle cell trait. The employees sued alleging various statutory and constitutional violations including the violation of the right to privacy. The district court had dismissed the claims but the court of appeals remanded observing that “[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one’s health or genetic make-up.”<sup>67</sup>

### Federal Statutes

#### Privacy Act of 1974

Certain federal statutes may provide some privacy protection for medical records. The Privacy Act of 1974, 5 U.S.C. § 552a, prohibits the disclosure of records maintained on individuals by federal government agencies except under certain conditions. Subsection 552a(f)(3) allows agencies to establish special procedures for individuals who wish to access their medical records. The intent of this provision as described in the House report was to ensure rules so that an individual who would be adversely affected by the receipt of such data may be apprized of it in a manner which would not cause such adverse effects.<sup>68</sup>

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<sup>64</sup> See e.g., *Whalen v. Roe*, 429 U.S. 589 (1977).

<sup>65</sup> For a more detailed discussion of this issue see Gostin, “Genetic Privacy,” 23 *J. of Law, Medicine & Ethics* 320 (1995).

<sup>66</sup> 135 F.3d 1260 (9<sup>th</sup> Cir. 1998).

<sup>67</sup> *Id.* at 1269. The ninth circuit also noted that the tests at issue “may also be viewed as searches in violation of Fourth Amendment rights.”

<sup>68</sup> H.Rept. 93-1416. 93d Cong., 2d Sess. 16-17 (1974).

## The Freedom of Information Act (FOIA)

The Freedom of Information Act (FOIA), 5 U.S.C. §§ 552 et seq., establishes a right of access to records maintained by agencies within the executive branch of the federal government. It contains several exemptions, including one for “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.”<sup>69</sup> Both the Privacy Act and FOIA may, then, provide some privacy protections for genetic information but they are limited in their scope and would not encompass information held by a private entity.<sup>70</sup>

## The Americans with Disabilities Act (ADA)

The ADA provides for some privacy protections for individuals with disabilities in the context of employment. Before an offer of employment is made, an employer may not ask a disability related question or require a medical examination.<sup>71</sup> The EEOC in its guidance on this issue stated that the rationale for this exclusion was to isolate an employer’s consideration of an applicant’s non-medical qualifications from any consideration of the applicant’s medical condition.<sup>72</sup> Once an offer is made, disability related questions and medical examinations are permitted as long as all individuals who have been offered a job in that category are asked the same questions and given the same examinations.<sup>73</sup> The ADA also requires that information obtained regarding medical information be kept in a separate medical file.<sup>74</sup> The precise reach of the protections, especially regarding predictive genetic information is uncertain. As was discussed previously, it is not clear whether the definition of disability under the ADA would cover an individual with a genetic predisposition to a condition when that condition has not manifested.<sup>75</sup>

## The Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) contains requirements for the standardization of electronically transmitted health insurance financial claims and administrative transactions, such as the submission of claims, processing of enrollments, verification of insurance eligibility, and payment and remittance advice. HIPAA required the Secretary of Health and Human Services (HHS) to make recommendations to Congress by August 1997 concerning the protection of privacy of individually identifiable health information and Congress had until August 1999 to enact legislation on this issue. If Congress did not enact legislation, HIPAA

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<sup>69</sup> 5 U.S.C. § 552(b)(6).

<sup>70</sup> For a discussion of recent developments in medical records privacy, see CRS Report RS20500, *Medical Records Privacy: Questions and Answers on the HIPAA Rule*, by C. Stephen Redhead.

<sup>71</sup> 42 U.S.C. § 12112.

<sup>72</sup> EEOC, “ADA Enforcement Guidance: Preemployment Disability-Related Questions and Medical Examinations,” Oct. 10, 1995.

<sup>73</sup> *Id.*

<sup>74</sup> 42 U.S.C. § 12112(d)(3) and (4).

<sup>75</sup> One commentator has observed that “the complexity of the ADA, its differential treatment of prospective and existing employees, the especially wide latitude that employers have to require medical examinations and make medical inquiries at the post-offer stage and the centrality of the concept of ‘disability’ to the operation of the statute have led to confusion in the courts, and in many workplaces, about the precise contours of the ADA’s privacy protections.” Joanne L. Hustead and Janlori Goldman, “The Genetics Revolution: Conflicts, Challenges, and Conundra: Genetics and Privacy,” 28 *Am. J. L. and Med.* 285, 294 (2002).

requires the Secretary of HHS to promulgate regulations on privacy protections. The Secretary of HHS issued final regulations on December 20, 2000.<sup>76</sup>

The final privacy regulations, which became effective on April 14, 2001, and were modified on August 14, 2002,<sup>77</sup> apply to health insurers, providers, and health care clearinghouses and give patients the right to inspect, copy and in certain situations, amend their medical records. The regulations cover all personal health information in paper, oral or electronic form. Individually identifiable health information is defined broadly and includes genetic information as well as information about an individual's family history.<sup>78</sup> Covered entities are required to have in place reasonable safeguards to protect the privacy of patient information and limit the information used or disclosed to the minimum amount necessary to accomplish the intended purpose of the disclosure. Civil money penalties are provided, although there is no private right of action, and egregious violations carry federal criminal penalties of up to \$250,000 and ten years in prison. Although these regulations are general and not specific to genetics, they will have an effect on genetic information. In the comments to the regulations, the Department noted that many commentators requested additional protections for sensitive information, including genetic information. In response, the Department noted that generally the regulations do not differentiate among types of protected health information.<sup>79</sup>

## State Statutes

Although there is limited federal law relating to the use of genetic information, many states have enacted statutes dealing with various aspects of these issues. Early state statutes focused on particular genetic conditions. The first statute to prohibit discrimination based on a genetic trait was enacted in North Carolina and prohibited employment discrimination based on the sickle cell trait. In 1991 Wisconsin became the first state to enact a comprehensive law to prohibit discrimination based on genetic test results. Currently, the states vary in their provisions with some prohibiting discrimination in employment while others deal solely with discrimination in insurance. A recent survey of state law found that thirty-four states have enacted genetic nondiscrimination in employment laws.<sup>80</sup> These laws vary and the National Conference of State Legislatures noted:

All laws prohibit discrimination based on the results of genetic tests; many extend the protections to inherited characteristics, and some include test results of family members, family history and information about genetic testing, such as the receipt of genetic services. Most states also restrict employer access to genetic information, with some prohibiting employers from requesting, requiring and obtaining genetic information or genetic test results, or directly or indirectly performing or administering genetic tests. Some states may

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<sup>76</sup> 65 Fed. Reg. 82461 (Dec. 20, 2000). For a more detailed discussion, see CRS Report RS20500, *Medical Records Privacy: Questions and Answers on the HIPAA Rule*, by C. Stephen Redhead, and CRS Report RS20934, *A Brief Summary of the HIPAA Medical Privacy Rule*, by Gina Stevens.

<sup>77</sup> 67 Fed. Reg. 53181 (Aug. 14, 2002).

<sup>78</sup> There are additional protections regarding "psychotherapy notes."

<sup>79</sup> 65 Fed. Reg. 82731 (Dec. 20, 2000). A hearing in the 107<sup>th</sup> Congress examined the issues relating to the privacy of genetic information. See "Privacy Concerns Raised by the Collection and Use of Genetic Information by Employers and Insurers" Before the House Subcommittee on the Constitution of the House Judiciary Committee, 107<sup>th</sup> Cong., 2d Sess. (September 12, 2002).

<sup>80</sup> National Conference of State Legislatures Genetics Tables, State Genetics Employment Laws, <http://www.ncsl.org/programs/health/genetics/ndiscrim.htm>.

also make exceptions to statutory requirements if, for example, genetic information may identify individuals who may be a safety risk in the workplace.<sup>81</sup>

A related survey found that forty-seven states have passed laws pertaining to the use of genetic information in health insurance.<sup>82</sup> Many state genetic laws also include specific provisions relating to genetic privacy.<sup>83</sup> In a recent survey, twenty-seven states were found to require consent to disclose genetic information while seventeen states require informed consent for a third party to perform or require a genetic test or obtain genetic information. Eighteen states were found which establish specific penalties for violating genetic privacy laws.<sup>84</sup>

Although these state statutes do provide some types of coverage, they do not cover employer self-funded plans providing private health insurance for employees and their dependents. These plans are exempt from state insurance laws due to the preemption provision in the federal Employee Retirement Income Security Act (ERISA).<sup>85</sup> Since it has been estimated that over one-third of the nonelderly insured population obtains its coverage through self-funded plans and these types of plans are increasing, the ERISA exemption limits the application of state laws significantly.<sup>86</sup>

## Federal Legislation

### Legislation in the 110<sup>th</sup> Congress

H.R. 493, the Genetic Information Nondiscrimination Act of 2007 (GINA), was introduced by Representative Slaughter and 143 cosponsors on January 16, 2007. After being reported out of the House Education and Labor Committee, the House Energy and Commerce Committee, and the House Ways and Means Committee, the bill passed the House on April 25, 2007, by a vote of 420 to 3. H.R. 493, as passed by the House, contains provisions prohibiting genetic discrimination in health insurance (Title I) and in employment (Title II). On March 5, 2008, the text of H.R. 493 as passed by the House was added to the end of the Paul Wellstone Mental Health and Addiction Equity Act of 2007 (H.R. 1424) in the engrossment of H.R. 1424.<sup>87</sup> On April 24, 2008, the Senate took up H.R. 493, replaced the existing language with an amendment in the nature of a substitute, and passed the measure, as amended, by a vote of 95-0. H.R. 493, as amended and passed by the Senate, is very similar to the version passed by the House last year. The most significant difference is new language strengthening the “firewall” between Title I and Title II of the act. The House is expected to pass H.R. 493 (as amended) during the week of April 28, 2008.

Senator Snowe, joined by 22 cosponsors, introduced S. 358, a companion bill to H.R. 493, on January 22, 2007. Senator Snowe noted in her introductory remarks that “in June of 2003, after sixteen months of bipartisan negotiation, we achieved a unified, bipartisan agreement to address

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<sup>81</sup> *Id.*

<sup>82</sup> National Conference of State Legislatures Genetics Tables, State Genetic Nondiscrimination in Health Insurance, <http://www.ncsl.org/programs/health/genetics/ndishlth.htm>.

<sup>83</sup> National Conference of State Legislatures Genetics Tables, State Genetic Privacy Laws, <http://www.ncsl.org/programs/health/genetics/prt.htm>.

<sup>84</sup> *Id.*

<sup>85</sup> 29 U.S.C. §§ 1001-1145.

<sup>86</sup> Hudson, “Genetic Discrimination and Health Insurance: an Urgent Need for Reform,” 270 Science 391 (1995); Rothenberg, “Genetic Information and Health Insurance: State Legislative Approaches,” 23 *J. of Law, Med. & Ethics* 312 (1995).

<sup>87</sup> The Senate passed S. 558, Mental Health Parity Act of 2007 on September 18, 2007.

genetic discrimination. Today we again introduce the legislation encompassing that agreement, which the Senate has twice passed ... unanimously.”<sup>88</sup> S. 358, which, like H.R. 493, contains provisions prohibiting genetic discrimination in health insurance (Title I) and in employment (Title II), was reported out of the Senate Health, Education, Labor, and Pensions Committee on March 29, 2007.

H.R. 493, as passed originally by the House and most recently by the Senate, prohibits health insurance plans from denying enrollment or charging higher premiums to individuals or groups based on an individual’s or family member’s genetic information. It also prohibits health insurance plans from requesting or requiring that any individual, or family member of an individual, undergo a genetic test. In addition, it contains privacy provisions amending the HIPAA statute to require revisions in the HIPAA Privacy Rule prohibiting certain uses and disclosures of genetic information.

H.R. 493, as passed originally by the House and most recently by the Senate, provides that references to genetic information include genetic information on a fetus carried by a pregnant woman and, with respect to an individual utilizing assisted reproductive technology, includes genetic information of any embryo legally held by the individual or family member. H.R. 493 allows group health plans to obtain genetic information for purposes of payment, and allows a plan to request that an individual undergo a genetic test for the purposes of research, but the plan must make clear that this would be entirely voluntary on the part of the individual and would not be used for underwriting purposes.

H.R. 493, as passed originally by the House and most recently by the Senate, also prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. If such information is obtained, the bill requires that it be treated as part of a confidential medical record and provides that an employer is considered to be in compliance with the maintenance of information requirements if the genetic information is treated as a confidential record under § 102(d)(3)(B) of the Americans with Disabilities Act.<sup>89</sup> In addition, the bill does not prohibit an entity covered by regulations promulgated pursuant to part C of Title XI of the Social Security Act<sup>90</sup> or section 264 of the Health Insurance Portability and Accountability Act<sup>91</sup> from any use or disclosure of health information that is authorized by those regulations. H.R. 493 adds a provision in Title II, like that in Title I, relating to the genetic information of a fetus or embryo. There are detailed provisions on enforcement that generally apply the remedies available in existing civil rights laws such as Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e-4 *et seq.*

On January 17, 2007, the White House issued a statement calling upon Congress to pass genetic nondiscrimination legislation. The administration praised the Senate for passing a bipartisan genetic nondiscrimination bill in the 109<sup>th</sup> Congress and noted that “the Administration looks to build on that success and work with both houses of Congress, and the business community, to pass a bill the President can sign into law.”<sup>92</sup> The news release noted the importance of genetic nondiscrimination protections for the ability to use new genetic technologies, and observed that “the President believes it is critical that an individual’s personal genetic information not be used

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<sup>88</sup> 153 CONG. REC. S. 846 (Daily Ed. Jan. 22, 2007).

<sup>89</sup> 42 U.S.C. § 12112(d)(3)(B).

<sup>90</sup> 42 U.S.C. § 1320d *et seq.*

<sup>91</sup> 42 U.S.C. § 1320d-2 note.

<sup>92</sup> See <http://www.whitehouse.gov/news/releases/2007/01/print/20070117-1.html>.



by an employer to deny a job....[and] that insurance companies do not use genetic information to deny an application for coverage.”<sup>93</sup>

## **Legislation in the 109<sup>th</sup> Congress**

In the 109<sup>th</sup> Congress, S. 306, the Genetic Information Nondiscrimination Act of 2005, was introduced by Senator Snowe on February 7, 2005. The Senate Health, Education, Labor and Pensions Committee reported S. 306 out with an amendment in the nature of a substitute by a voice vote. The bill was passed, with an amendment, on February 17, 2005 by a vote of 98-0. The amendment deleted former section 103 which would have added a prohibition of discrimination based on genetic information or services in church health insurance plans to the Internal Revenue Code. The Administration indicated that it favored enactment of legislation to prohibit the improper use of genetic information in health insurance and employment and supported the enactment of S. 306, 109<sup>th</sup> Congress.<sup>94</sup> A companion bill, H.R. 1227, was introduced in the House on March 10, 2005 by Representative Biggert. H.R. 1227 was referred to the House Committees on Education and the Workforce, Energy and Commerce, and Ways and Means.

S. 306 was similar to S. 1053, which passed the Senate in 2003. It prohibits health insurance plans from denying enrollment or charging higher premiums to individuals based on the individual's or family member's genetic information. In addition, it contains privacy provisions prohibiting certain uses and disclosures of genetic information as well as prohibiting the collection of genetic information for insurance underwriting purposes. S. 306 also prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. If such information is obtained, the bill requires that it be treated as part of a confidential medical record. There are detailed provisions on enforcement which generally apply the remedies available in existing civil rights laws such as Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e-4 et seq.

Another bill, H.R. 6125, 109<sup>th</sup> Congress, was introduced in the House on September 20, 2006 by Representative Paul. This bill would have prohibited discrimination based on genetic information by certain group health plans and in employment by federal, state or local entities or recipients of federal financial assistance or contractors. Employees or family members who have been adversely effected would have had a cause of action in federal court for compensatory and punitive damages, with the punitive damages limited to no more than 30% of compensatory damages.

## **Legislation in the 108<sup>th</sup> Congress**

Several bills were introduced in the 108<sup>th</sup> Congress to address genetic discrimination and privacy. For example, S. 16, the Equal Rights and Equal Dignity for Americans Act of 2003 introduced by Senator Daschle on January 17, 2003, contained nondiscrimination provisions relating to insurance and employment. On May 1, 2003, Representative Slaughter introduced H.R. 1910, The Genetic Nondiscrimination in Health Insurance and Employment Act, which prohibited genetic discrimination in insurance and employment. H.R. 1910 was a companion to S. 1053, introduced by Senator Snowe on May 13, 2003, in the Senate.

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<sup>93</sup> *Id.*

<sup>94</sup> “Statement of Administration Policy, S. 306—Genetic Information Nondiscrimination Act of 2005,” reprinted in 151 Cong. Rec. S. 1481 (Daily ed. Feb 16, 2005).



On October 14, 2003, the Senate passed the Genetic Information Nondiscrimination Act of 2003 (S. 1053).<sup>95</sup> This bill prohibited health insurance plans from denying enrollment or charging higher premiums to individuals based on the individual's or family member's genetic information. In addition, the bill banned the collection, use and disclosure of genetic information for insurance underwriting purposes. In the employment context, this bill prohibited the use of genetic information in employment decisions, such as hiring, firing, job assignments and promotions. The bill also prevented the acquisition and disclosure of genetic information as well as applies the procedures and remedies authorized under the Civil Rights Act of 1964 to cases of genetic discrimination. Although President Bush supported genetic discrimination legislation and the House held a hearing in July 2004,<sup>96</sup> the House did not pass a bill in the 108<sup>th</sup> Congress.

## **Legislation in the 107<sup>th</sup> Congress**

Legislation relating to genetic discrimination and privacy was a major issue in the 107<sup>th</sup> Congress. The Senate version of the Patient Protection Act, S. 1052, which passed the Senate on June 29, 2001, contained an amendment prohibiting certain genetic discrimination by group health plans and health insurance issuers. It also contains a provision relating to confidentiality. Congress did not pass the legislation prior to the adjournment of the 107<sup>th</sup> Congress.

Other Senate legislation in the 107<sup>th</sup> took various approaches. S. 318, introduced by Senator Daschle, would have prohibited genetic nondiscrimination in health insurance and employment. S. 1995 sponsored by Senators Snowe, Frist and Jeffords, also would have prohibited genetic discrimination in insurance and employment but was less broad than S. 318. S. 19, the Protecting Civil Rights for all Americans Act introduced by Senator Daschle, contained nondiscrimination provisions relating to insurance and employment. Senator Snowe also introduced S. 382, the Genetic Information Nondiscrimination in Health Insurance Act of 2001, which would have prohibited discrimination in insurance. S. 450, the Financial Institution Privacy Protection Act of 2001 introduced by Senator Nelson, contained provisions protection the privacy of health information, including genetic information.<sup>97</sup>

In the House, Representative Slaughter introduced H.R. 602, the Genetic Nondiscrimination in Health Insurance and Employment Act, which would have prohibited genetic discrimination in insurance and employment. H.R. 602 was paralleled by S. 318 in the Senate.

## **Legislation in the 106<sup>th</sup> Congress**

Although legislation specifically relating to genetic discrimination and privacy was not enacted during the 106<sup>th</sup> Congress, a provision relating to health insurance was considered in the conference on H.R. 2990. The Senate amended H.R. 2990 as passed by the House, striking all the language after the enacting clause and substituting the language in S. 1344. This Senate bill would have amended ERISA, the Public Health Service Act and the Internal Revenue Code to prohibit health plans or health insurance issuers, in both group and individual markets, from using predictive genetic information to set premiums. It also contained confidentiality provisions.

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<sup>95</sup> 149 Cong. Rec. S12394-12508 (daily ed. Oct. 4, 2003).

<sup>96</sup> "Genetic Non-Discrimination: Examining the Implications for Workers and Employers" Subcommittee on Employer-Employee Relations, House Committee on Education and Workforce (July 22, 2004).

<sup>97</sup> For a more detailed discussion of this legislation, see CRS Report RS20185, *Privacy Protection for Customer Financial Information*, by M. Maureen Murphy.

Senator Daschle had offered a more comprehensive amendment to the FY2001 Labor-HHS Appropriations bill, S. 2553. It would have prohibited insurance companies from raising

premiums or denying coverage on the basis of genetic tests and would have also barred employers from using predictive genetic information to make employment-related decisions. The amendment was defeated by a vote of 54-44.

## **Author Information**

Nancy Lee Jones  
Legislative Attorney

Amanda K. Sarata  
Analyst in Health Policy and Genetics

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